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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,467	03/30/2004	Anna Marie Aguinaldo	A-71431-4	7268

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EXAMINER

HISSONG, BRUCE D

ART UNIT PAPER NUMBER

1646

DATE MAILED: 09/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/820,467

Applicant(s)

AGUINALDO ET AL.

Examiner

Bruce D. Hissong, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 6-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-5, in the reply filed on 8/25/2006, is acknowledged.

2. Applicant's election with traverse of modification of interferon (IFN)- β at position 8 in the reply filed on 8/25/2006 is acknowledged. The traversal is on the ground(s) that MPEP § 803.04 states "normally ten sequences constitute a reasonable number for examination purposes. Accordingly, in *most* cases, *up to ten* independent and distinct nucleotide sequences will be examined in a single application without restriction" (emphasis added). The Applicants also argue that the modified positions are single amino acid modifications of the same original sequence, and therefore the search burden is reduced. Additionally, the Applicants argue that the substitutions are all in the same class and subclass.

These arguments have been fully considered and are not found persuasive. Each of the claimed substitutions would result in a polypeptide with a different sequence, and thus different physical/biochemical characteristics. MPEP § 806.04(b) states "Species may be either independent or related under the particular disclosure. Where species under a claimed genus are not connected in any of design, operation, or effect under the disclosure, the species are independent inventions." In the instant case, each of the claimed substitutions would produce polypeptides with a different sequence and therefore are not connected by design. Furthermore, it is noted that searching each of the claimed substitutions, alone or in combination, represents an undue search burden because any search of a mutation(s) involves searching the mutation(s) itself, and the effect of the mutation(s) on the polypeptide. Finally, regarding MPEP § 803.04, it is noted that this USPTO policy was set forth in response to applications drawn to the examination of many sequences such as expressed sequence tags (ESTs), and the claimed variant IFN- β polypeptide is not an EST. It is also noted that the language of the MPEP states that "up to" 10 sequences (i.e. a maximum of 10 sequences rather than a minimum of 10 sequences) will be examined in "most" cases.

The requirement is still deemed proper and is therefore made FINAL.

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3. Claims 1-15 are currently pending. Claims 6-15 are withdrawn as non-elected subject matter, and claims 1-5 are the subject of this office action.

Claim Objections

1. Claims 1-5 are objected to for reciting non-elected subject matter. Due to Applicants' election of a substitution at position 8, the recitation of other substitution positions in claim 1 constitutes non-elected subject matter. Claims 2-5 are objected to for depending from claim 1.

2. Claim 3 is objected to for the following informality: The claim contains an extra period at the end of the sentence.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-5 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are drawn to variant IFN proteins that may already be present in nature, and as written, do not show the "hand of man" in the inventive process. This rejection may be obviated by amending the claims to recite an "*isolated variant*".

Claim Rejections - 35 USC § 112, first paragraph - enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the variant type I IFN- β polypeptides comprising a substitution at position 8 as described in the examples of the specification, does not reasonably provide enablement for any other variant type I IFN- β comprising a substitution at position 8.

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The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors to be considered when determining if the disclosure satisfies the enablement requirement have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breath of claims. *Ex Parte Forman*, (230 USPQ 546 (Bd. Pat. App. & Int. 1986); *In re Wands*, 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

In the instant case, the breadth of the claims is excessive because the claims read on any variant of type I IFN- β comprised of at least one modification, wherein that modification is a substitution at position 8, and wherein said protein exhibits modified immunogenicity compared to wild-type IFN- β . The specification is enabling for the various IFN- β polypeptides comprising a substitution at position 8 that are described in the examples. However, as written, the claimed polypeptides can be any IFN- β polypeptide that contains a substitution at any amino acid, as long as the polypeptide contains a substitution at position 8. Given the broadest possible interpretation, the claims could read on a polypeptide resulting from substitution at all amino acid residues. There is no guidance or examples in the specification that teach an IFN- β polypeptide with unlimited substitutions that exhibits modified immunogenicity compared to wild-type IFN- β , wherein the modified immunogenicity is either increased, or decreased due to increased solubility. A person of ordinary skill in the art would not be able to predict which amino acid residues of IFN- β , other than those described in the examples of the specification, could be substituted and result in a polypeptide with either increased or decreased immunogenicity, reduced solubility, or reduced binding to at least one human class II MHC allele. It is known in the art that even single amino acid changes or differences in the amino acid sequence of a protein can have dramatic effects on the protein's function. As an example of the unpredictable effects of mutations on protein function, Mickel *et al* (Med. Clin. North Am., 2000, Vol. 84(3), p. 597-607) teaches that cystic fibrosis is an autosomal recessive disorder caused by abnormal function of a chloride channel, referred to as the cystic fibrosis transmembrane conductance regulator (CFTR – p. 597). Several mutations can cause cystic fibrosis, including the G551D mutation. In this mutation, a glycine replaces the aspartic acid at position 551, giving rise to the cystic fibrosis phenotype. In the most common cystic fibrosis

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mutation, Δ -F508, a single phenylalanine is deleted at position 508, giving rise to the cystic fibrosis phenotype. Thus, even the substitution or deletion of a single amino acid can have dramatic and *unpredictable* effects on the function of the protein.

Therefore, while a person of ordinary skill in the art would be able to make and use the various IFN- β polypeptides comprised of a substitution at position 8 that are taught in the specification and meet the limitations of the claims, the excessive breadth of the claims regarding IFN- β variants with unlimited modifications, the lack of guidance and examples in the specification showing such variants, and the unpredictability of the art would lead to undue experimentation to determine which other IFN- β amino acid residues could be substituted and result in a polypeptide that meets the limitations of the claims of the instant application.

2. Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a variant IFN- β polypeptide comprising a modification at position 8 that exhibits decreased immunogenicity, does not reasonably provide enablement for a variant IFN- β polypeptide comprising a modification at position 8 that exhibits increased immunogenicity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims of the instant invention are drawn to variant IFN- β polypeptides exhibiting modified immunogenicity. Due to the Applicants' election of a modification at position 8, the claims are specifically drawn to a variant IFN- β polypeptide modified at position 8 that exhibits modified immunogenicity. Claims 2 and 5 are further drawn to variant IFN- β polypeptides comprising a modification at position 8 that exhibit reduced or increased immunogenicity, respectively. Although the specification provides examples of IFN- β polypeptides modified at position 8 and having reduced immunogenicity as defined by increased solubility, the specification does not provide guidance or examples showing how to make and use a variant IFN- β polypeptide having a modification at position 8 and exhibiting increased immunogenicity. Due to the unpredictability inherent in the art regarding the effects of modifying amino acid residues of proteins, a person of ordinary skill in the art would not be able to predict how to make and use a variant IFN- β polypeptide that exhibits increased immunogenicity without further, undue experimentation.

Claim Rejections - 35 USC § 112, first paragraph – written description

Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a variant type I IFN- β polypeptide exhibiting modified immunogenicity compared to wild-type IFN- β , and comprised of a substitution at position 8. Although the specification does disclose variant IFN- β polypeptides substituted at position 8 and having modified immunogenicity, these examples are not sufficient to adequately describe the claimed genus of variant IFN- β polypeptides. As set forth above in the 35 U.S.C. 112, 1st paragraph enablement rejection, as written, the claims read on a variant IFN- β polypeptide substituted in any position, as long as position 8 is substituted. The claims do not require the variant IFN- β polypeptides of the instant invention to have any particular structure other than contain an amino acid that was substituted at position 8, and does not teach which other amino acid residues can be substituted and result in a variant polypeptide with either increased or reduced immunogenicity, increased solubility, or reduced binding to at least one human class II allele. Thus, the claims are drawn to a genus of variant polypeptides that have not been adequately described in the instant specification.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claims is a requirement that the variant IFN- β polypeptide contain a substitution at position 8. There is no identification of any particular portion of a variant IFN- β polypeptide that must be conserved in order to maintain the desired immunogenicity, solubility, or ability to bind human class II MHC alleles. Accordingly, in the absence of sufficient distinguishing characteristics, the specification does not provide adequate written description of the claimed genus.

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Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is drawn to a variant type I IFN- β polypeptide comprised of a modification at position 8. The claim does not specify, or identify by sequence identifier, any wild-type IFN- β polypeptide sequence upon which the variant IFN- β polypeptide is derived. As written, the claim reads on variant IFN- β polypeptides from any species. Additionally, the variant IFN- β polypeptide of the instant application could be derived, for example, from the mature 166 amino acid human IFN- β polypeptide, or the immature 187 amino acid IFN- β polypeptide that contains a signal sequence. Thus, the metes and bounds of the variant type I IFN- β polypeptide cannot be determined and the claim is therefore indefinite. Furthermore, the metes and bounds of "position 8" cannot be determined because it is not known if position 8 is relative to the start of immature human IFN- β , mature human IFN- β , or IFN- β from another species. Claims 2-5 are also rejected for depending from rejected claim 1.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Runkel *et al* (*Biochem.* 2000, Vol. 39, p. 2538-2551). The claims of the instant invention are drawn to a variant type I IFN- β polypeptide exhibiting modified immunogenicity, increased solubility, and reduced binding to at least one human class II MHC allele, wherein said IFN- β variant comprises a substitution at position 8, and wherein substitution mutations are selected from

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alanine, arginine, aspartic acid, asparagine, glutamic acid, glutamine, glycine, histidine, and lysine. Runkel *et al* teaches variant IFN- β polypeptides, including an IFN- β polypeptide comprising an alanine substitution at position 8 (see Figure 1A). Although Runkel *et al* is silent regarding modified or reduced immunogenicity, increased solubility, or reduced binding to at least one human class II MHC allele, it would be expected, in the absence of evidence to the contrary, that the IFN- β polypeptide disclosed by Runkel *et al* in Figure 1A would inherently possess these features due to the substitution at position 8, and the examples in the instant specification showing IFN- β polypeptides substituted at position 8 meet the claimed limitations regarding solubility and immunogenicity. Because the USPTO does not have the facilities for testing the properties of the disclosed IFN- β variant of Runkel *et al*, the burden is on the applicant to show a novel and unobvious difference between the claimed IFN variant and that of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.). Therefore, the IFN- β variant disclosed by Runkel *et al* meets the limitations of claims 1-4 of the instant application.

2. Claims 1-4 are rejected under 35 U.S.C. 102(a) as being anticipated by Pedersen *et al* (US 6,531,122). The subject matter of the claims of the instant invention is discussed *supra*. Pedersen *et al* teaches IFN- β variants produced for the purpose of conjugation to various polymers. Specifically, Pedersen teaches replacement of various amino acids, including the phenylalanine at position 8 (F8), with other amino acids such as lysine (column 14, line 54 – column 15, line 20), aspartic acid or glutamic acid (column 17, line 58 – column 18, line 38). Thus, Pedersen *et al* discloses an IFN- β variant with a substitution at position 8. In addition, Pedersen *et al* disclose IFN- β molecules with modified (decreased) immunogenicity (column 13, lines 16-38). Furthermore, even if Pedersen *et al* did not specifically teach modified/decreased immunogenicity, it would be expected, in the absence of evidence to the contrary, that the IFN- β variants comprising a substitution of lysine or glutamic acid at position 8 would inherently exhibit increased solubility relative to a wild-type IFN- β , and exhibit reduced immunogenicity compared to a wild-type IFN- β polypeptide because IFN- β polypeptides comprising a substitution at position 8 are disclosed by the instant specification as having these properties. Because the USPTO does not have the facilities for testing the properties of the disclosed IFN- β variant of Pedersen *et al*, the burden is on the applicant to show a novel and unobvious difference between the claimed IFN variant and that of the prior art. See *In re Best*, 562 F.2d 1252, 195

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USPQ 430 (CCPA 1977) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

3. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Bell *et al* (US 4,738,844). The subject matter of the claims of the instant invention is discussed *supra*. Bell *et al* teach modified IFN- β polypeptides comprised of various amino acid substitutions. Specifically, Bell *et al* teaches mutant IFN- β polypeptides produced by substitution of various amino acids, and teaches that amino acids 1-28 of IFN- β can be replaced by any other naturally occurring amino acid, including alanine, arginine, aspartic acid, asparagine, glutamic acid, glutamine, glycine, histidine, and lysine (column 4, lines 43-61). Bell *et al* also teaches an IFN- β polypeptide in which amino acids 3-28 have been replaced by amino acids 2-26 of IFN- α (see Example 4 and claim 4), resulting in a substitution of a histidine at position 8 (see columns 23-24 – Chart 3d showing amino acid sequence of this polypeptide). Therefore, Bell *et al* teaches an IFN- β polypeptide comprising a substitution at position 8. Although Bell *et al* is silent regarding modified or reduced immunogenicity, increased solubility, or reduced binding to at least one human class II MHC allele, it would be expected, in the absence of evidence to the contrary, that the IFN- β polypeptide disclosed by Bell *et al* in Chart 3d/Claim 4 would inherently possess these features due to the substitution at position 8, and the examples in the instant specification showing IFN- β polypeptides substituted at position 8 meet the claimed limitations regarding solubility and immunogenicity. Because the USPTO does not have the facilities for testing the properties of the disclosed IFN- β variant of Bell *et al*, the burden is on the applicant to show a novel and unobvious difference between the claimed IFN variant and that of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.). Therefore, the IFN- β variant disclosed by Bell *et al* meets the limitations of claims 1-4 of the instant application.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined

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application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 7, 10-12, 27-28, and 35 of copending Application No. 10/676,705. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The subject matter of the claims of the instant application is discussed *supra*. Copending Application No. 10/676,705 is drawn to a variant type I IFN- β polypeptide comprising a modification at position 8, and specifically a F8E substitution, as set forth in the Applicant's election received on 6/2/2006. Thus, the claims of both the instant application and copending application 10/676,705 are drawn to a variant IFN- β polypeptide comprising a modification at position 8. Claim 1 of the instant application recites a modification at position 8 wherein the substituted amino acid is glutamic acid, and therefore the claims of both applications encompass the same variant IFN-b polypeptide. Furthermore, both applications recite variant IFN- β polypeptides with modified (reduced) immunogenicity and increased solubility. Therefore, because the subject matter of both copending applications overlap significantly, it would be obvious to one of ordinary skill in the art to practice the claims of the instant invention by following the claims of copending application 10/676/705. Finally, although the claims of the instant application do not recite a pharmaceutical composition comprised of a variant type I IFN-b polypeptide, because both applications teach the polypeptide, it would be obvious to a skilled artisan to make a pharmaceutical composition comprised of the polypeptide.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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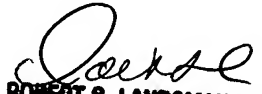
Conclusion

No claim is allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce D. Hissong, Ph.D., whose telephone number is (571) 272-3324. The examiner can normally be reached M-F from 8:30am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, Ph.D., can be reached at (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BDH
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ROBERT S. LANDSMAN, PH.D.
PRIMARY EXAMINER